UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,827	05/23/2007	Quinton Van Rooyen	44.P001	7183

52418 7590 12/23/2011

HAHN AND MOODLEY, LLP
3333 Bowers Avenue
Suite 130
Santa Clara, CA 95054

EXAMINER	
BREDEFELD, RACHAEL EVA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
12/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

devasena@hahnmoodley.com
vani@hahnmoodley.com
daya@hahnmoodley.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,827	ROOYEN ET AL.	
	Examiner	Art Unit	
	RACHAEL WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6-8 and 12-14* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-8 and 14* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment

Applicant is advised that the examiner assigned to this application has changed. The examiner currently assigned to this application is **Rachael Bredefeld**, whose contact information can be found at the end of the action. Receipt of the amendments and arguments/remarks filed on 8/16/11 is acknowledged.

Claim Status

Claims 4, 6-8, and 12-14 are pending. Claim 14 is newly added. Claims 12-13 are withdrawn. Claims 1-3, 5, and 9-11 are cancelled.

Claim Objections

The objections to claim 1 are withdrawn in light of applicant's amendments.

Withdrawn Rejections

The rejection of claims 1, 5, 8 and 11 under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14, 1995) in view of Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) is withdrawn in light of applicant's amendments.

The rejection of claims 1, 4, 7 and 9 under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14, 1995) in view of Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) as applied to claims 1, 5, 8 and 11 and further

in view of Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999) is withdrawn in light of applicant's amendments.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14, 1995), Visser et al. (WO 98/56325) (pub. Dec. 17, 1998) and Landauer et al. (WO 99/13885) (pub. Mar. 25, 1999) as applied to claims 1, 4-9 and 11 above, and further in view of Reed (US 5,827,530) (pub. Oct. 27, 1998) is withdrawn in light of applicant's amendments.

New Rejections/Objections Necessitated by Applicant's Amendments

Claim Objections

Claim 14 is objected to because of the following informalities. Claim 14 should recite "is impervious" instead of "in impervious." This appears to be a typo. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-8, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites "a composite distal layer" and then recites "the composite proximal layer" when referring to where the proximal layer is adhesively secured.

However, it is not clear if there are two composite layers (i.e., both a composite proximal layer and a composite distal layer) or if applicant intended to recite "the composite distal layer" instead of "the composite proximal layer." Applicant's clarification is respectfully requested. For purposes of examination, the examiner will interpret the claim to read on only one composite layer and more specifically, a composite distal layer.

Claims 4 and 8 are dependent on claim 15. However, currently, claim 15 is not a pending claim. Thus, the scope of claims 4 and 8 are unclear because one cannot ascertain what or which limitations are in claim 15. Appropriate correction is required. For purposes of examination, the examiner will be interpreting claims 4 and 8 to be dependent on claim 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6-8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. (WO 95/24172) in view of Visser et al. (WO 98/56325), Landauer et al. (WO 99/13885) and Reed (US 5,827,530).

Ebert et al teach a transdermal delivery device comprising an impermeable backing material laminated to an adhesive layer (abstract and figure). The device further comprises a gelled drug layer between the distal adhesive layer and the proximal adhesive layer (abstract and figure). The adhesive layers are laminated together (pg. 6). The backing material may be a silicone elastomer (pg. 15). The distal and proximal adhesive layers may be the same and the distal and proximal layers may each be composite layers (pg. 17). The distal and proximal layers may be semi-permeable to the drug and the thickness may be adjusted, for example to have quick release from the proximal layer and sustained release from the distal layer (pg. 17). Suitable adhesives include polysiloxanes (p. 16). The device of Ebert et al also contains a proximal release liner that covers the skin-facing side of the device until it is used (pg. 18).

Ebert et al do not teach that a substance may be injected into the patch through an access port in the backing layer which leads to a transverse passage extending through the distal layers into a cavity.

Landauer et al teach that indirect administration of DMF may be done by introducing a known amount of DMF with a syringe into the silicon dioxide adsorbent of its patch after it has been applied to the skin (pg. 17). According to Landauer et al, this indirect administration has the advantage of giving a predetermined therapeutic agent dosage according to a patient's profile (pg. 17). Furthermore, the administration allows for the patch and agent to be easily administered and applied without any worries of overdosing (pg. 18).

Reed teaches a fillable transdermal delivery device that utilizes injection ports for post assembly introduction of medicinally active agents (abstract). The fillable reservoir of the transdermal device is filled by means of loading a needle with the active agent and inserting the needle through the septum of the loading port (abstract).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to administer a substance via a syringe to the transdermal patch of Ebert et al. One would have been motivated to do so since Landauer et al teach that this type of administration has the advantage of giving a predetermined therapeutic agent dosage according to a patient's profile. Additionally, one would have a reasonable expectation of success that the administration allows for the patch and agent to be easily administered and applied without any worries of overdosing.

Furthermore, it would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use an injection port for injecting a substance into the patch reservoir. One would have been motivated to do so because this allows the person injecting the substance to inject into the reservoir and not into another part of

the patch. Moreover, Reed provides a shield in the interior of the fillable reservoir to protect the diffusion membrane from damage in the event that the needle is inserted too far.

Regarding claim 4, Ebert et al do not teach that the active agent to be delivered is dimethylformamide (DMF). However, Visser et al and Landauer et al teach the transdermal administration of dimethylformamide (DMF). Visser et al teach DMF is used to treat a viral or microbial infection and that the drug is absorbed through the skin at 9.4 mg/cm^2/hr (pg. 1 and 27). Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Ebert et al, Visser et al and Landauer et al and to use the transdermal delivery device of Ebert et al to deliver DMF. One would have been motivated to do so because Ebert et al teach that the term "drug" or "pharmacologically active agent" means any chemical or biological material suitable for transdermal administration, including antiinfectives (pp. 8-9) and Visser et al teach that DMF is a drug that may be transdermally delivered to treat viral or microbial infections. Furthermore, the selection of a particular active ingredient for use in a composition is considered prima facie obvious since it depends on the symptoms and diseases being treated.

Regarding the functional language of claims 4 and 14, the invention as claimed is not structurally distinguishable from the combination of Ebert et al, Visser et al, Landauer et al, and Reed. Therefore, it is the examiner's position that permeability of the irritating component of the substance (DMF) is less than the permeability of human/animal skin and that the patch reduces the irritation of the human/animal skin.

Alternatively, since the permeability of DMF in the human skin is known (Visser et al, pg. 27), it would have been within the purview of the skilled artisan to modify the thickness of the proximal and distal layers to adjust permeability, as is suggested by Ebert et al.

Regarding claim 7, Visser et al teach that DMF is absorbed through the skin at 9.4 mg/cm^2/hr (p. 27). MPEP 2144.05 states that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties" (quoting *Titanium Metals Corp. of America v. Banner,* 778 F.2d 775, 227 USPQ 774 (Fed. Cir. 1985)). In the instant case, about 9.4 mg/cm^2/hr is so close to 9 mg/cm^2/hr that the patch is expected to have the same permeability properties and reduction in buildup of DMF on the skin of the patient.

Regarding claim 8, Visser et al teach that colloidal silicone dioxide is impregnated with DMF (pg. 26). As evidenced by the instant specification, the solid filler material can be colloidal silicone dioxide (see pg. 6, lines 10-14 of spec.).

Response to Arguments

Applicant's arguments filed 8/16/11 have been fully considered but they are not persuasive.

Applicant argues that Ebert does not teach a backing sheet having a peripheral area by which the patch may be adhered to a patient and an access port via which a syringe may be used to inject a substance into the cavity formed in the patch. Applicant

further argues that Visser and Landauer also fail to disclose the limitation of a backing sheet. Applicant argues that Landauer does not describe the structures of an access port or a passage.

In response to applicant's arguments, it is noted that the new rejections necessitated by applicant's amendments above are based on the combination of Ebert, Visser, Landauer, and Reed. All the instant claims are rejected over the four references. Applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Landauer and Reed teach injecting a substance into the cavity of a patch and more specifically Reed teaches an access port and transverse passage in a patch. Additionally, Ebert teaches a transdermal patch with a backing sheet. Thus, it is the examiner's position that the combination of references teaches all the limitations of the instant claims. The claims are rendered obvious in view of the entire art of record.

Conclusion

Claims 4, 6-8, and 14 are rejected. No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL BREDEFELD (WELTER) whose telephone number is (571)270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. E. B./
Examiner, Art Unit 1611

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611